Section 5

SEP 08 2009

K091562

LAMBDA Scientifica SpA

510(K) SUMMARY

510(k) owner and submitter	LAMBDA Scientifica S.p.A. Via Retrone 39 36077 Altavilla Vicentina (Vicenza) Italy +39 0444 349 165 +39 0444 349 954
Contact person	Mr Boschi Alessandro +39 0444 349 165 boschi@lambdascientifica.com
The common name of the device	Diode laser
Trade name / Propietary names	Doctor Smile A-810, B-980 Lasers
Classification name	Laser surgical instrument for use in general and plastic surgery and dermatology
Product code	Gex
CFR Number	21 CFR §878.4810
Predicate Devices	*Doctor Smile A-810, B-980:Lasers* - Arc Laser GmbH Fox Q-810, Q-980 K073322 - Biolase Ezlase® K082938 - Sirona Sirolaser K053161 - Kavo Gentleray 980 K072262 - Ceralas 980 K072779 - Claros Nano Dental Laser System K081652
Product description	Doctor Smile A-810, B-980 Lasers are the same standard diode medical lasers respectively with 810, 980 nm wavelength.
Intended Use	Doctor Smile A-810 Laser is intended for use in the following procedure: Soft Tissue, Laser Periodontal procedures and tooth whitening. Intra- and extra oral surgery including incision, excision, vaporization, ablation, haemostasis and coagulation of oral soft tissues, Laser soft tissue curettage, whitening. Doctor Smile Diode B-980 Laser is intended for use in the following procedure: Surgical applications requiring the ablation, vaporization, excision, incision, haemostasis, or coagulation of soft tissue in medical specialties including dentistry, dermatology, general surgery, gynecology, opthamology, pulmonology, otolaryngology, othopedics.

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http://www.lambdascientifica.com - E-Mail: info@lambdascientifica.com
Cap. Soc. Euro 500.000,00 – C.F. e P. I.V.A. 02558810244 - Registro Imprese di Vicenza n. 199230/96

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Performance standards	The Doctor Smile A-810, B-980 Lasers comply with the following standards: IEC 60601-1:1998+A1:1991+A2:1995 IEC 60601-2-22:1995 IEC 60825-1:1993+A1:1997+A2:2001 21 CFR 1040.10 and 1040.11
Device technological characteristics and Comparison to Predicate device(s)	Doctor Smile A-810, B-980 Lasers are portable instruments which transmit laser energy via a contact fiber optic delivery system and each unit is compromised of the following main components: -a laser system console (including display panel, software and control); -a fiber optic delivery system; -one or more handpieces -protective eye ware Doctor Smile Diode A-810, B-980 Lasers have the same intended use and the same or substantially equivalent technical specifications and mechanism of action as compared with the named predicated devices.
Conclusion:	The Doctor Smile A-810, B-980 Lasers have identical or similar indications for use, principles of operation, overall technical and functional capabilities. Therefore is substantially equivalent to the predicate devices. They have similar intended uses and comply with the same safety and performance standards.

Review: *Boschi Alessandro*

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 08 2009

Lambda Scientifica S.p.A
% Mr. Boschi Alessandro
Via Retrone 39
36077 Altavilla Vicentina
Italy

Re: K091562
Trade/Device Name: Doctor Smile A-810 B-980 Lasers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 1, 2009
Received: September 1, 2009

Dear Mr. Alessandro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Peter D Pfendler MD MPH
Dep Dir

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

LAMBDA Scientifica SpA

Indications for Use

510(k) Number (if known): _____

Device name: Doctor Smile A-810, B-980 Lasers

Doctor Smile A-810 Laser is intended for use in the following procedure:

Soft Tissue, Laser Periodontal procedures and tooth whitening Intra- and extra oral surgery including incision, excision, vaporization, ablation, haemostasis and coagulation of oral soft tissues, Laser soft tissue curettage, whitening.

Following specific indications: Excisional and incisional biopsies, Exposure of unerupted teeth, Fibroma removal, Frenectomy, Frenotomy, Gingival troughing for crown impressions, Gingivectomy, Gingivoplasty, Gingival incision and excision
Haemostasis and coagulation, Implant recovery, Incision and drainage of abscess
Leukoplakia, Operculectomy, Oral papillectomies, Pulpotomy, Pulpotomy as an adjunct to root canal therapy, Reduction of gingival hypertrophy, Soft tissue crown lengthening, Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa, Vestibuloplasty. Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket. Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.). Light activation of whitening/bleaching material.

Doctor Smile B-980 Laser is intended for use in the following procedure:

Surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissue in medical specialties including dentistry, gastroenterology, dermatology, general surgery, gynecology, opthamology, pulmonology, otolaryngology, othopedics.

Dental applications:
Frenectomy, Frenotomy, Biopsy, Operculectomy, Implant Recovery, Gingivectomy, Gingivoplasty, Gingival Troughing, Crown Lengthening, Haemostasis of Donor Site, Removal of Granulation Tissue, Laser-assisted Flap Surgery, Debridement of Deseased Epithelial Lining, Incisions and Draining of Abscesses, Tissue Retraction for Impressions, Papillectomy, Vestibuloplasty, Excision of Lesions, Leukoplakia, Exposure of Unerupted/Partially Erupted Teeth, Removal of Hyperplastic Tissues, Treatment of Aphthous Ulcers, Sulcular Debridement, Pulpotomy, Pulpotomy as an Adjunct to Root Canal Therapy, and Light Activation of Bleaching Materials

Prescription use____XX___ and/or Over-the-counter use_____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Review: *Boschi Alessandro*

510(k) Number K091562

Laser Equipment - Sensori e Sistemi di Monitoraggio / *Monitoring Systems and sensors*
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